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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,792	06/22/2001	Tobias Meyer	0459-0570P	9673

2292 7590 07/16/2003

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 07/16/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/787,792

Applicant(s)

MEYER, TOBIAS

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 11-25 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11, 13-25 and 46-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15, 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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**DETAILED ACTION**

***Election/Restrictions***

***Response to Arguments***

Applicants argue that the non-elected species of claim 12 should be rejoined with the elected claims because of the improper nature of the examiner's prior art rejection. In response, the inadvertent inclusion of this non-elected species in the prior art rejection is regretted. However, since this claim is drawn to the non-elected species, hence, this claim is withdrawn from consideration. Also, the inadvertent inclusion of the non-elected claim 7 in the rejection in the last Office action is regretted. Since claim 7 has been cancelled hence, applicants' statement is moot.

***Status of Claims***

Claims 7-10 and 26-45 have been cancelled in the present amendment, 5/8/03. Claims 47-49 have been added.

Claim 12 is withdrawn from consideration as being drawn to non-elected species.

Claims 1-6, 11, 13-25 and 46-49 are pending and under examination.

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***Specification***

The disclosure is objected to because of the following informalities for the reasons advanced in the last Office action and addressed as they appear in therein:

***Response to Arguments***

1. Applicants argue that the label of Figure 1E appears to have been obscured by the photocopy submitted to the PTO. This issue will be corrected once formal drawings are submitted. In response, in the absence of said formal drawings the objection to the specification is maintained.

2. In view of the amendments to the claims, the objection with respect to spelling errors is withdrawn.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 4, 47 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The as-filed specification does not provide a description by which the first heterologous conjugate is separately expressed from the second heterologous conjugate. Applicants cite page 25, lines 6-10 of the specification as support. The cited section recites expression of a fusion protein and not a first or second heterologous conjugate. (Claim 1). Likewise, claim 47 which recites a detectable group **derived** from GFP is not supported in the as-filed specification. ( See specifically page 6, lines 6-24 as stated by applicants). The original disclosure does not describe how the detectable signal has been derived from GFP. Also, the step in claim 48 is not described in the as-filed specification, specifically page 10, lines 5-6 as pointed out by applicants.

Claims 1-6, 11, 13-25 and 46-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for GFP as the detectable group and isoforms of CaMKII  $\alpha$  and  $\beta$ , does not reasonably provide enablement for a first and second heterologous protein conjugates, fragments of the protein and any type of cell for reasons advanced in the last Office action.

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***Response to Arguments***

Applicants submit "concerning the first and second proteins interest, that it is exactly these proteins which may be unknown. Rather, it is the mechanism currently claimed which is to be used in the determination of binding interactions between the first and second proteins of interest" is unclear. This argument does not obviate the lack of enabling disclosure as stated in the last Office action.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Newly amended claims 1-6, 11, 13-25 and 46-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons set forth in the last Office action.

***Response to Arguments***

A). Applicants argue that the amendment to claim 1 clearly defining more the required steps render the rejection moot. In reply, there are no new method steps that are recited in the amended claim. This rejection is maintained.

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Applicants fail to respond to the following rejections i.e., the terms "first" and "second" are relative terms. It is not clear from the claimed context the differentiating characteristics or features of these claims. "Protein of interest" is ambiguous as to the basis by which of said protein selection. Since applicant has not responded to these rejections, it is believed that applicants are acquiescing therewith.

B). Applicant states that the amendment to the claim clarifies the issue with respect to claims 3 and 5. In reply, the amended claims are so confusing as to whether each of the heterologous conjugates is expressed separately by the cells.

C). Applicants argue that the amendment to claim 6 obviate this rejection. In response, it is not clear as to the need for a method of interacting two known proteins.

D). The inadvertent rejection of claim 7 is regretted. In view of the cancellation of claim 7, the argument is moot.

E). Applicants argue that in claims 24 and 25 "different" refers to distinct proteins. In reply, these are two of the same thing.

The following rejections are apply to the newly amended claims:

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1. Claim 47 is unclear as to how the detectable group is **derived** from GFP.

2. Claim 48 does not add further limitation to the base claim. This limitation is already recited in the base claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11, 13-25 and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Knippschild et al (Oncogene, 1997) for reasons set forth in the last Office action.

***Response to Arguments***

Applicants argue that Knippschild discloses only a single fusion protein of gamma and epsilon kinase with GFP. Knippschild fails to suggest or disclose utilizing a second protein of interest fused to a known protein. In response, attention is directed to the full text of Knippschild, submitted by applicants at e.g., page 1734 col. 2, third complete paragraph up to page 1735, col. 2. Knippschild discloses two fusion



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proteins of GST-p53 and GST-CK1 $\alpha$  and GST-CK1 $\epsilon$  or GFP-CK1 $\alpha$  and GFP-CK1 $\epsilon$ .

Claims 1-6, 11, 13-25 and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by anyone of Benfenati et al (Nature) or Chen et al (Neuron) or Llinas et al (Jrnl. of physiology).

Each of these discloses a method of detecting protein protein interaction comprising using fusion proteins. See Benfenati e.g., abstract, page 417. Also, the abstract of Chen at page 895. Llinas at e.g., page 259 starting with the Methods section. Accordingly, the specific process steps of each of these references using specific fusion components anticipate the broad claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 11, 13-25 and 46-49 rejected under 35 U.S.C. 103(a) as being unpatentable over Knippschild in view of

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Shirai (Jpn. J. Pharmacol.) or Oancea et al (The Journal of Cell Biology).

Knippschild is discussed above. Knippschild does not disclose the step of inducing translocation comprises adding a phorbol ester, as recited. Shirai discloses at e.g., page 143, col. 1, treatment with phorbol ester to present a visible translocation of the PKC isoforms. Said phorbol ester treatment show a decrease in the cytosol fraction and increase in the particulate fraction with said ester. Oancea basically discloses the use of phorbol ester as Shirai. See e.g., the abstract, page 485. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use phorbol ester in the method of Knippschild for a more visible translocation of the PKC, as taught by Shirai or Oancea.

No claim is allowed.

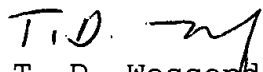
Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw  
7/13/03